

REMARKS

Claims 1-5, 11-28 and 43-49 have been amended. Claims 6-10, 29-42 and 50-69 have been cancelled and new Claims 70-82 have been added. Accordingly, Claims 1-5, 11-28, 43-49 and 70-82 remain presented for examination. Applicants reserve the right to prosecute non-elected claims in a divisional or continuation application.

Support for new Claims 70-82 can be found throughout the specification. Claims 70-77 find particular support with reference to Figure 5. Claims 78-82 find particular support with reference to Figures 19-20.

Discussion of Figure 23

The Examiner indicated that replacement Figure 23, as presented on June 3, 2002, was unacceptable and alleged that the replacement drawing contained new matter for illustrating additional features at the bottom of the figure. Applicants respectfully disagree.

As is described throughout the application, the target zones 148 are associated with fluidic circuits 138 so that an incident beam that is projected through the underside of the optical bio-disc can penetrate the reflective layer of the substrate 146 and contact the sample loaded within the fluid circuit 138. This is clearly seen in Figures 25 and 26 which provide additional views of the bio-disc illustrated in Figure 23.

For this reason, it would be clear to one of ordinary skill in the art upon reading the specification, that the target zones 148 align with the fluidic circuits 138, and are preferably not offset, as illustrated in original Figure 23. For this reason, Applicants' amendment to Figure 23 to indicate that the target zones 148 align with the fluidic circuits 138 is not new matter, and was in fact fully described in the application as filed.

However, solely to advance prosecution of this application, and because the target zones 148 of Figure 23 are shown to align with some of the fluidic circuits 138, Applicants request entry of the original Figure 23, attached herewith. For this reason, Applicants respectfully request withdrawal of this rejection.

Discussion of Rejections Under 35 U.S.C. § 112

The Examiner rejected Claims 1-5, 11-30, 43-49 and 65 as being allegedly indefinite for reciting the term "optical bio-disc." The Examiner argued that the claims did not include optical

components, and thus it was unclear whether the claimed bio-disc was an optical bio-disc. Applicants respectfully disagree.

Applicants' use of the term "optical bio-disc" is fully explained in the specification which indicates that an optical bio-disc is used with an optical disc drive such as a CDROM, DVD or other well-known disc drive that reads such discs using a laser source. This is explained with reference to Figures 1 and 2, beginning on page 13, at line 13. However, solely to advance prosecution of the application, Applicants have removed the term "optical" from the claims to indicate that any type of bio-disc that includes the claimed elements is within the scope of Applicants invention. Accordingly, Applicants respectfully request withdrawal of this rejection.

The Examiner also rejected independent Claims 1, 6, 11, 16, 21, 26-29 and 43 for reciting characteristics of a reactive group, but not describing immobilized DNA. Applicants have amended these claims to more specifically recite that the DNA is immobilized onto a surface. Accordingly, Applicants respectfully request withdrawal of this rejection.

The Examiner also rejected Claims 26-29, 30 and 65 for reciting a function of the input site, but not the structural components of the bio-disc. Applicants have amended claims 26-28 to remove this language from the claims. Thus, Applicants respectfully request withdrawal of this rejection.

The Examiner rejected claim 30 as being indefinite for reciting an intended use of the bio-disc. This rejection is now moot, as Applicants have cancelled claim 30.

For all of the above reasons, Applicants respectfully request withdrawal of the rejections relating to 35 U.S.C. § 112

Discussion of Rejections Under 35 U.S.C. § 102

The Examiner rejected claims 1-4, 6-9, 21-24, 43-46 and 49 under 35 U.S.C. § 102(e) as being anticipated by Hammock et al. (U.S. Patent No. 6,395,562). The Examiner argued that Hammock et al. disclosed an optical bio-disc having a circular substrate having a center and an outer edge, an active layer associated with the substrate, and a strand of DNA including a reactive group attached to the active layer to immobilize a strand of DNA. Applicants respectfully disagree.

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367,

1379 (Fed. Cir. 1986). “Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention.” *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Hammock et al. describe a compact assay system that uses a solid support, such as a compact disc, to perform assays. The surface of the compact disc is treated with reagents that are immobilized on the surface of the compact disc using a miniaturized printing system. In one embodiment, the reagents are applied to the surface of the compact disc using an ink jet printer. The printed surface of the compact disc is then exposed to compounds to be tested for binding to the immobilized reagents.

This contrasts with Claims 1-4, 6-9, 21-24, 43-46 and 49, which relate to a bio-disc which includes a fluidic circuit, or flow channel, which communicates with an active layer containing immobilized DNA. As described in the specification, the fluidic circuit is typically formed by stamping or cutting a membrane into a desired shape in order to provide flow channels within the bio-disc. No such structure is described by Hammock et al.

Accordingly, as Hammock et al. do not directly or inherently teach bio-discs having fluidic circuits or flow channels, this reference cannot anticipate Claims 1-4, 6-9, 21-24, 43-46 and 49. For this reason, Applicants respectfully request withdrawal of this rejection.

The Examiner also rejected claims 16-19, 65 and 66 under 35 U.S.C. § 102(e) as being anticipated by Hammock et al. as defined by Sigma. The Examiner argued that Hammock et al. disclose an optical bio-disc comprising a circular substrate, an active layer associated with the substrate and a strand of DNA including a reactive group having affinity for the active layer. The Examiner commented that Sigma defines avidin as being an amino reactive group. Applicants respectfully disagree.

As discussed above, Hammock et al. teach an assay system that utilizes an ink jet printer to immobilize reactants on the surface of a compact disc. This contrasts with Claims 16-19, 65 and 66 which relate to bio-discs having a fluidic circuit, or flow channel. Neither Hammock et al. nor Sigma describe such a structure, either directly or inherently. Thus, Applicants respectfully request withdrawal of this rejection.

The Examiner rejected Claims 6 and 9-10 under 35 U.S.C. § 102(b) as being anticipated by Charles et al. (U.S. Patent No. 5,439,972). Applicants respectfully traverse. However as Claims 6-10 have been cancelled, this rejection is now moot.

The Examiner rejected Claims 1-4, 6-9, 11-14, 16-19, 21-24, 43-46 and 65-66 under 35 U.S.C. § 102(b) as being anticipated by Wang et al. (U.S. Patent No. 5,922,617). The Examiner argued that Wang et al. disclose a bio-disc having a substantially circular substrate, an active layer associated with the substrate and a strand of DNA having a reactive group with affinity to the active layer. Applicants respectfully disagree.

Wang et al. describe an assay system similar to the system described by Hammock et al. As described in Wang, et al., various species of reagents are immobilized at specific sites on a compact disc using ink jet printing, silk printing, offset printing, stamping or mechanical application (column 5, lines 31-46). Each of these techniques involves immobilizing a desired reagent to the surface of a compact disc. The compact disc is then contacted with a solution containing a component to be tested (column 9, lines 26-55).

This differs from Claims 1-4, 6-9, 11-14, 16-19, 21-24, 43-46 and 65-66, which include a membrane associated with an active layer wherein the membrane comprises a fluidic circuit, or flow channel. Wang et al. do not describe any such membrane or fluidic circuit as their technique relies upon placing reagents on the surface of a compact disc. There is no teaching of providing an active layer that communicates with a fluidic circuit. As Wang et al. do not directly or inherently describe a bio-disc having such features, they cannot anticipate the rejected claims. For this reason, Applicants respectfully request withdrawal of this rejection.

The Examiner rejected claims 1-3, 6-8, 11-13, 16-18, 21-23, 26-30, 43-45 and 65-66 under 35 U.S.C. § 102(b) as being anticipated by Virtanen (U.S. Patent No. 6,342,349). The Examiner argued that Virtanen disclosed a bio-disc having a circular substrate, an active layer associated with the substrate and a strand of DNA having affinity for the active layer. The Examiner also argued with regard to claims 26-30 that Virtanen disclosed a flow channel in fluid communication with a target zone deposited in the flow channel and an input site in fluid communication with the flow channel for receiving sample DNA as allegedly described in Figures 19 and 40. Applicants respectfully disagree.

Virtanen describes various types of optical disc-based assay devices in which analyte-specific elements are immobilized on an optical disc substrate. Virtanen also describes nucleic acid hybridization assays in chemical detection. With regard to Figure 19, Virtanen describes an assay device adapted for continuous monitoring that includes application inlets for spatially segregated assay sectors. The assay device illustrated in Figure 19 includes a substrate 53 substantially parallel to, and separated from, a substrate 20, with a gap therebetween forming a sample cavity through which sample flows from the sample inlet to the sample outlet (column 53, lines 64 to column 54, line 6). Preferably, the assay device is made of two discs of optically clear polycarbonate which are formed during manufacture to have a hollow interior which creates the resulting cavity (column 54, lines 24-37). With regard to Figure 40, Applicants note that this is a description of a vacuum well-plate as described at column 62, beginning at line 1. The vacuum well plate is a reusable manifold that is connected to a vacuum source in order to provide a reusable system for applying samples to a bio-disc. The well plate is contacted with a film, as shown in Figure 41, and then evacuated to provide wells. These wells are then filled with sample solutions and contacted by a bio-disc. This process is illustrated in reference to Figures 41A-L.

Virtanen does not describe a bio-disc having an active layer and a membrane associated with the active layer, wherein the membrane comprises a fluidic circuit, or flow channel. As described in Virtanen, the flow channel illustrated in Figure 20 is made by sandwiching two discs together while providing a gap between the discs. For this reason, Virtanen does not describe each and every element of Applicants' claims. Moreover, the use of such a membrane provides significant advantages over the sample cavity illustrated by Virtanen. For example, the fluidic circuit can be designed in a variety of shapes, such as a "U" shape, as illustrated in Figure 3 of Applicants' application. Although Applicants' invention is not related to any particular design of a fluidic circuit, or flow channel, the use of such a membrane provides flexibility that is not found with the sample cavity described by Virtanen. For this reason, Figure 19 of Virtanen does not teach each and every element of Applicants' claims.

With regard to Claims 26-28, Applicants note that Virtanen does not describe a target zone associated with the substrate, wherein the capture DNA is detectable through the target zone. With regard to Claim 43, Virtanen does not describe a reflective layer comprising openings defining a plurality of target zones.

Moreover, as discussed above, the vacuum well plate described by Figure 40 does not teach each and every element of the rejected claims. This well plate is not a bio-disc, nor does it include an active layer having capture DNA immobilized thereon. As illustrated in Figure 41, the vacuum well plate is contacted with a bio-disc in order to provide an assay system. Thus, Figure 40 does not teach each and every element of Applicants' claims.

For all of the reasons cited above, Applicants respectfully request withdrawal of all rejections under 35 U.S.C. § 102 and allowance of the pending claims.

Discussion of Rejections Under 35 U.S.C. § 103

Claims 5, 10, 20, 25 and 48 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Hammock et al. in view of Charles et al. (U.S. Patent No. 5,436,972) and/or Jan et al. (U.S. Patent No. 6,403,368). The Examiner argued that claims 5, 20, 25 and 48 were taught by Hammock et al. except that they do not teach that the polystyrene was a polystyrene-co-maleic anhydride. The Examiner argued that such compounds were well known, as taught by Charles et al. and Jan et al. Applicants respectfully disagree.

To establish a *prima facie* case of obviousness a three-prong test must be met. First, there must be some suggestion or motivation, either in the references or in the knowledge generally available among those of ordinary skill in the art, to modify the reference. Second, there must be a reasonable expectation of success found in the prior art. Third, the prior art must reference must teach or suggest all the claim limitations. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

As discussed previously, Hammock et al. do not teach bio-discs as recited in the rejected claims. For example, there is no teaching in Hammock et al. of a membrane associated with an active layer on a substrate wherein the membrane comprises a fluidic circuit. For this reason, and the arguments provided above, the combination of Hammock et al. with Charles et al. or Jan et al. do not teach each and every element of the rejected Claims. Accordingly, this combination would not make Claims 5, 10, 20, 25 and 48 obvious to one of ordinary skill in the art. For this reason, Applicants respectfully request withdrawal of this rejection.

The Examiner also rejected claims 5, 10, 15, 20, 25 and 48 under 35 U.S.C. § 103(a) as being unpatentable over Wang et al. in view of Charles et al. and/or Jan et al. The Examiner argued that Wang et al. disclose a bio-disc having a tracking groove, a reflective layer, an active layer associated with a substrate and a strand of DNA having affinity for the active layer. The Examiner argued that although Wang et al. do not teach that a polystyrene is a polysytrene-co-maleic anhydride and that this compound was allegedly known in the art as evidenced by Charles et al. and Jan et al. Applicants respectfully disagree.

As described above, Wang et al. do not teach a bio-disc as recited in the rejected claims. For example, Wang et al. do not teach a bio-disc having a membrane associated with an active layer wherein the membrane comprises a fluidic circuit. Thus, the combination of Wang et al. with Jan et al. or Charles et al. do not teach each and every limitation of the rejected claims. For this reason, the combination of these references would not make the rejected claims obvious to one of ordinary skill in the art. Accordingly, Applicants respectfully request withdrawal of this rejection.

The Examiner also rejected claims 26-30 under 35 U.S.C. § 103(a) as being unpatentable over Wang et al. in view of Burns et al. (U.S. Patent No. 6,379,929). The Examiner argued that Wang et al. teach a bio-disc having a substrate with encoded information associated therewith wherein the information is readable by a disc drive assembly to control rotation, a target zone associated with a substrate disposed at a predetermined location, an active layer associated with the target zone and a strand of DNA immobilized to the active layer. However, Wang et al. are silent regarding flow channels and input sites for sample introduction. The Examiner argued that Burns et al. teach a similar substrate wherein the device comprises a flow channel, plurality of reporters and an input site for receiving DNA sample to be analyzed. Applicants respectfully disagree.

Initially, Applicants note that Claims 29 and 30 have been cancelled, thus rendering their rejection moot. However, with respect to Claims 26-29, Applicants point out that neither Wang et al. nor Burns et al. describe a bio-disc having a substrate, a target zone associated with the substrate, an active layer associated with the target zone, and a strand of capture DNA immobilized on the active layer and detectable through the target zone. Nor do these references

show a flow channel in fluid communication with an active layer and adapted to receive a sample of target DNA.

As described above, Wang et al. describe compact discs with immobilized reagents printed to their surface. There is no teaching in Wang et al. of providing an active layer having immobilized capture DNA and detectable through a target zone. Moreover, combining Wang et al. with Burns et al. similarly does not cure this defect. There is no teaching in Burns et al. of a bio-disc having such a structure. In fact, Burns et al. describe a bio-assay chip having a reaction chamber with associated sensors, control circuitry and external connections. The Burns, et al. device is constructed from a silicon substrate to provide microfluidic device modules. There is no teaching of a device having capture DNA immobilized on an active layer and detectable through a target zone. Accordingly, the combination of Wang et al. and Burns et al. does not teach each and every element of the claims. Accordingly, such a combination would not make Claims 26-30 obvious to one of ordinary skill in the art. For this reason, Applicants respectfully request withdrawal of this rejection and allowance of the pending claims.

Discussion of Double Patenting

The Examiner provisionally rejected Claims 11-15 and 21-30 under the doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 29-66 of co-pending application 10/086,941. As the co-pending application has not yet been allowed, Applicants respectfully request that this rejection be held in abeyance until such time as the '941 application becomes patented.

Conclusion

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any

remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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